

REMARKS/ARGUMENTS

In this response, no claims are being amended, added, or canceled. Thus, claims 1-23, 35-48, 50-60, 62, and 63 remain pending in the application. Reconsideration of this application is respectfully requested in view of the remarks below.

Claim Rejections – Obviousness-Type Double Patenting

The Office Action provisionally rejected claims 38, 41, and 56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of copending application no. 10/734,599. In response, Applicants are submitting herewith a terminal disclaimer with respect to the '599 application. Withdrawal of the rejection is requested.

The Office Action also provisionally rejected claims 38, 41, and 56 on the ground of nonstatutory obviousness-type double patenting as being “unpatentable over claims 1-94 of copending application no. 10/733,869.” In response, Applicants point out that the '869 application is no longer pending because it issued as U.S. Patent 7,319,900 on Jan. 15, 2008, with 88 claims. Applicants are submitting herewith a terminal disclaimer with respect to the '900 patent. Withdrawal of the rejection is requested.

Applicants wish to point out that a continuation of the '869 application was filed on Jan. 15, 2008, and is now pending as U.S. application serial no. 12/008,876.

Claim Rejections - § 112

The Office Action rejected claims 1-23, 35-60 [sic: 35-48 and 50-60], and 62-63 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. These rejections center around the words “using only the single cardiac signal” in independent claims 1, 15, 35, 57, 59, and 62, and similar words (“using only the sensed cardiac signal”) in independent claims 39 and 52. The Examiner cited MPEP § 2173.05(i), and stated that the language “using only the single cardiac signal” is not disclosed in the original disclosure “and thus fails to comply with the written description requirement.” Applicants respectfully submit that this rejection cannot be sustained,

because there are clear and ample teachings in the as-filed application to support the disputed terminology.

To begin with, the Examiner is correct when he says that the *language* “using only the single cardiac signal” is not in the original disclosure. If that were the standard to determine compliance with 35 U.S.C. §112, first paragraph, then the claims would indeed be properly rejected under that statute. However, that is not the appropriate standard. For example, *in haec verba* support for claimed subject matter is not required. See *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Note in this regard the warning in MPEP § 2173.05(i) that “a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support.”

Rather, under the written description requirement, the disclosure “must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention.” *Crown Operations International v. Solutia Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002). The requirement is satisfied by the patentee’s disclosure of such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. See *Id.* Put another way, one skilled in the art, reading the original disclosure, “must reasonably discern the limitation at issue in the claims.” *Id.* With this as the appropriate standard for compliance with first paragraph of §112, the as-filed application can be seen to clearly support the disputed language.

We turn first to claim 1, reproduced here with the disputed language italicized:

1. A method of determining a cardiac response to a pacing pulse, comprising:
 - providing a plurality of electrodes electrically coupled to a heart;
 - delivering the pacing pulse to the heart using a first electrode combination;
 - sensing a single cardiac signal for cardiac response classification following the pacing pulse using a second electrode combination; and
 - classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion/pseudofusion beat *using only the single cardiac signal.*

The person skilled in the art, reading the original disclosure, would reasonably discern all of these limitations, including the italicized portion. Such person would discern the “providing a plurality of electrodes ...” at least in connection with Applicants’ FIG. 1 and its description. He or she would discern the remaining “delivering”, “sensing”, and “classifying” actions in a number of places, but we will focus on Applicants’ FIG. 12, reproduced below, and its associated description:

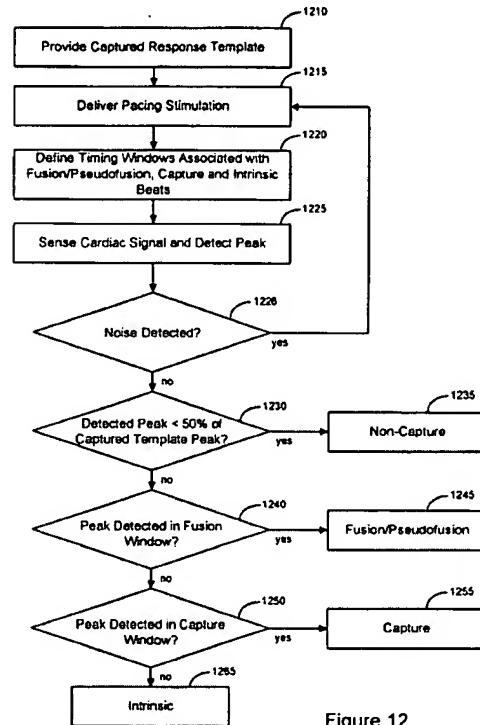


Figure 12

The skilled person reads at page 9 lines 1-3 that FIG. 12 “is a flowchart illustrating a method of classifying a cardiac response using fusion, capture, and intrinsic classification windows in accordance with an embodiment of the invention.” The person then reads the detailed description of the figure, from line 19 of page 42 to line 27 of page 43, in which the entire process from box 1210 through box 1265 is explained. The person discerns from the figure and the description that a pacing pulse is delivered to the heart at box 1215, and that a single cardiac signal is sensed at box 1225, and the peak *of that same signal* is detected. (The person would have previously read at, for example, page 11 lines 11-18 that different electrode combinations for pacing and sensing can be used to enhance cardiac response

classification.) The person then discerns that, if no noise is detected, the cardiac response to the pacing pulse is classified as one of capture (box 1255), non-capture (box 1235), or fusion/pseudofusion (box 1245) by straightforward operation of the decision boxes 1250, 1230, and 1240 respectively. The person discerns from the decision boxes that these classifications are performed based on properties of the same cardiac signal, namely, the amplitude of the detected peak, and the detected peak's relative position with respect to the described classification windows.

Since the figure is described as “a flowchart illustrating a method of classifying a cardiac response ...”, the person reasonably expects that important aspects of the method are shown or described. Thus, it would be unreasonable for the person to expect an important aspect of the classification method to be omitted. Moreover, the person would consider it important to the method if a signal other than the particular cardiac signal described were used in the classification process. Hence, it would be unreasonable for the person to expect that a signal other than the particular cardiac signal described was used in the classification process. Put another way, the person reasonably discerns from FIG. 12 and its description that the classifying method uses the cardiac signal sensed at box 1225 and no other signal, i.e., that the classifying is performed “using only the single cardiac signal”.

The as-filed application can thus be seen to convey with reasonable clarity to those skilled in the art that the inventors were in possession of the invention now claimed in claim 1. Using the same analysis, we can show that the as-filed application conveys with reasonable clarity to those skilled in the art that the inventors were in possession of the invention now claimed in the other independent claims 15, 35, 39, 52, 57, 59, and 62. The rejections of the independent claims, and of their respective dependent claims 2-14, 16-23, 36-38, 40-48, 50, 51, 53-56, 58, 60, and 63 should therefore be withdrawn and the case should be passed to issuance.

Conclusion

For the foregoing reasons, the application is submitted to be in condition for allowance, the early indication of which is earnestly solicited. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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